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Testing whether a group-based early childhood program that includes fathers can improve child development in China

Submission date
31/01/2026

Recruitment status
Recruiting

Registration date
18/03/2026

Overall study status
Ongoing

Last Edited
16/03/2026

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
In China, underinvestment in developmental opportunities for young children by caregivers is a major cause of poor early childhood development (ECD) in rural households. The purpose of this study is to evaluate the effectiveness and scalability of a one-to-five group-based intervention (i.e., one training provider per five caregiver-child dyads providing parental training). The study will investigate whether such a program can effectively improve ECD and caregiver outcomes among communities in need (i.e., communities with a prevalence of developmental delay exceeding 20%). Additionally, the study will explore the potential benefits of involving non-primary caregiving fathers within such interventions.

Who can participate?
Primary caregivers and children (6-24 months of age) with a rural household registration status living in the selected communities at the time of baseline data collection.

What does the study involve?
The study will be undertaken in approximately 60 randomly selected geographical sample sites across twelve counties in Zhejiang Province, China. About 10 caregiver-child dyads will be randomly selected and divided into two age-based groups: (1) caregiver-child dyads below the overall sample mean (i.e., approximately 5 children aged 6-15 months) and (2) caregiver-child dyads above the overall sample mean (i.e., approximately 5 children aged 16-24 months). At each sample site, one of these age groups will be randomly assigned to the parental training intervention (treatment group), while the other age-group will be given no intervention (control or dummy intervention group), resulting in a total of 120 clusters (i.e., one treatment and one control cluster per sample site). Additionally, caregiver-child dyads in the treatment group will be assigned to a randomized father invitation arm. In the father invitation arm (30 clusters from all 12 counties, with 2 or 3 clusters per county), fathers will be invited to join the parental training sessions twice a month, either alone or with the primary caregiver.

What are the possible benefits and risks of participating?
This research will generate rigorous evidence on the impact of group-based ECD programs on

child psychosocial stimulation, caregiver mental health, and well-being. The potential benefits of this study include improved cognitive and non-cognitive skills of children, improved peer support and caregiver mental health. If this intervention is successful, its findings could inform future programs and policies aimed at improving the well-being of children and their caregivers in China. There are no possible risks of participation.

Where is the study run from?
Zhejiang University Medical School, USA.

When is the study starting and how long is it expected to run for?
November 2025 to January 2027

Who is funding the study?
1. Tsingshan Institute for Advanced Business Studies of Zhejiang University
2. ZJU-GENSCI Children's Health Research & Development Center
3. Zhejiang Enbao Charity Foundation

Who is the main contact?
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Contact information

Type(s)
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ZJU-GENSCI Children's Health Research & Development Center reference number
ZJU-GENSCI2024YY007

Study information

Scientific Title
Effectiveness and scalability of a father-inclusive group-based early childhood development program among children aged 0–3 years in China

Study objectives

This study aims to evaluate the impact of a randomised controlled trial testing the effects of a father-inclusive group-based parenting intervention by providing parenting guidance to parents (primary caregivers) of children aged 0-3 years with rural household registration in Zhejiang Province, living in both urban and rural areas. The project will cover twelve counties in Zhejiang Province. Intervention will be delivered to 60 clusters (i.e., approximately 300 families) assigned to the intervention group. Half of the treatment group (caregiver-child dyads from 30 clusters, from all 12 counties, with 2 or 3 clusters per county) will be assigned to the father invitation arm.

Specific research objectives:
1. To assess the current status of early childhood development of children aged 0-3 years in rural households in Zhejiang Province and the current parenting behaviours of their primary caregivers; and to explore possible differences depending on their area of residence (urban and rural).
2. To set up a total of 60 parenting centres in twelve counties in Zhejiang Province, and to provide free "one-on-five" parenting courses to families with children aged 0-3 years old in rural areas, to promote children's cognitive, language, and socio-emotional development, as well as in other developmental domains.
3. To assess whether inviting non-primary caregiving fathers (either alone or together with the primary caregiver) can improve the effectiveness of the parenting programme.
4. Effectively organizing and implementing an easy-to-operate and scalable service model for the early development of children aged 0-3 years through multisectoral cooperation and coordination (including the China's Health Commission, China's Education Bureau, the Ministry of Human Resources and Social Affairs).
5. Invite leaders from China's National Health Commission, the Maternal and Child Health Center, and other departments and the national project team to guide the implementation and evaluation of the project, to promote the results of the project as a national "template" for early development services for children aged 0-3 years.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/10/2025, Zhejiang University Medical School Ethics Committee (866 Yuhangtang Rd, Hangzhou, 310000, China; +86-571-87951395; yjsy-yb@zju.edu.cn), ref: 2024-IRB-0209-P-01

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose

Treatment

Study type(s)

Health condition(s) or problem(s) studied
Suboptimal early childhood development, including delays in cognitive, language, motor and socio-emotional development among children aged 0–3 years

Interventions
The present study is a group-based, prospective, cluster-randomized, controlled superiority trial. A random number generator was used to assign subjects to treatment and control.
Intervention group: group-based (i.e., one parental training provider per five caregiver-child dyads), parenting instruction sessions will be provided. Fathers in the father invitation arms will be invited to join the sessions twice a month (either alone or together with the primary caregiver).

Control group: No parental care instruction programme was provided.

To be more specific, in this study, a randomized controlled trial was conducted to randomly divide primary caregivers of children aged 0-3 years old with rural household registration in urban and rural communities in Zhejiang Province into an intervention group (providing parenting support) and a control group (not providing parenting support). In addition, caregiver-child dyads in the intervention group are assigned to a randomized father invitation arm. Prior to the start of the parenting support intervention, the project team conducted a baseline survey of the primary caregivers and children in the intervention and control groups to assess early childhood development outcomes under the status quo. After determining the prevalence of delay in each community, the project team will set up parenting centres (e.g., community-, township-, and village centres) in the sample districts and counties of Zhejiang Province, where more than 20% of children are found to be delayed at baseline. Interactive teaching aids and equipment for the "one-to-five" programme are provided at each site to support the "one-to-five" parenting guidance activities and promote the cognitive and language development of local children aged 0-3.

Based on the needs of the "one-to-five" parenting programme, the project team will select and train the required parenting trainers at the project sites. Through rigorous training and qualification, the childcare workers will master the content of the "one-to-five" curriculum and be able to provide individualized support to each child to promote his/her cognitive and language development. In each county, two or three training providers will be responsible for delivering the specific curriculum intervention at the sample sites. They will conduct weekly "one-on-five" parental training sessions with the primary caregivers of the children in the intervention group at the local parenting service station, for a total of nine months. The sessions will focus on parental counselling and guidance for early childhood development, providing systematic parenting support and ensuring that children receive ongoing care and education.

Fathers of the caregiver-child dyads that have been assigned to the father invitation arm will be invited to attend the parental training sessions twice a month, either alone or together with the primary caregiver. These sessions will follow the same scripted curriculum as the other sessions in the programme.

Intervention Type
Behavioural

Primary outcome(s)
1. Cognition, language and motor skills measured using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III) at baseline and at follow-up (i.e., after completion of the 9-month intervention program)

2. Social emotional skills measured using the Ages & Stages Questionnaire: Social-Emotional (ASQ:SE) at baseline and at follow-up (i.e., after completion of the 9-month intervention program)

Key secondary outcome(s))

Completion date
01/01/2027

Eligibility

Key inclusion criteria
1. Children aged 6 - 24 months of age and their caregivers living in the sample region at the time of baseline data collection
2. With a rural household registration status (hukou)
3. Willing to participate in the parenting support program
4. Willing to participate in the impact evaluation, including the child surveys, caregiver surveys, and household surveys
5. Able and willing to give informed consent

Healthy volunteers allowed
Yes

Age group
Child

Lower age limit
6 months

Upper age limit
24 months

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Children and caregivers who are not residing in the region
2. Children whose mothers have an urban household registration status
3. Children with severe disabilities
4. Caregivers who are unwilling or unable to give informed consent
5. Caregivers who are unwilling to participate in the intervention program

Date of first enrolment
15/11/2025

Date of final enrolment
01/10/2026

Locations

Countries of recruitment
China

Sponsor information

Organisation
Zhejiang University

ROR
https://ror.org/00a2xv884

Organisation
ZJU-GENSCI Children's Health Research and Development Center

Organisation
Zhejiang Enbao Charity Foundation

Funder(s)

Funder type

Funder Name
Zhejiang Enbao Charity Foundation

Funder Name
Tsingshan Institute for Advanced Business Studies of Zhejiang University

Funder Name
ZJU-GENSCI Children's Health Research and Development Center

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated and analyzed during the current study will be available upon request from Dr. Yun Shen (shenyun_@zju.edu.cn). De-identified data may be made available to researchers upon request and after careful reviewing of the research aim of the applying researcher. Oral consent was obtained from the interviewees and trial participants before survey administration and treatment enrollment. All datasets will be de-identified by removal of names, household IDs and village IDs.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	in Chinese version 1.2	15/10/2025	02/02/2026	No	Yes
Protocol file	in Chinese version 1.2	15/10/2025	02/02/2026	No	No